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Dated: March 8, 2006

ignature: (MACLA SIVERMAN)

Docket No.: AREX-P03-004

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Madiyalakan et al.

Application No.: 09/376,604

Confirmation No.: 6693

A.4.TT.'4 1640

Filed: August 18, 1999

Art Unit: 1642

For:

THERAPEUTIC COMPOSITIONS THAT

ALTER THE IMMUNE RESPONSE

Examiner: G. B. Nickol

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Supplemental Information Disclosure Statement is filed more than three months after the U.S. filing date, and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

Applicant submits herewith copies of the cited foreign patent documents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Supplemental Information Disclosure statement shall not be construed to be an

Application No.: 09/376,604 Docket No.: AREX-P03-004

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Supplemental Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 18-1945 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. AREX-P03-004. A duplicate copy of this paper is enclosed.

Dated: March 8, 2006

Respectfully submitted,

Gloria Fuentes

Registration No.: 47,580

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Attorneys/Agents For Applicant

PTO/SB/17 (12-04v2)
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Effective on 12/08/2004.				L	Complete if Known				
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).				4818).	Application Number 09/376,604				
FEE TRANSMITTAL					Filing Date	<del></del>	August 18, 1999		
For FY 2005					First Named Inv		Ragupathy Madiyalakan		
101112003					Examiner Name G. B. Nickol				
			See 37 CFR 1.27		Art Unit		642		
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FEE CALCUL	ATION								
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Utility		300	150	500	250	200	100		
Design		200	100	100	50	130	65		
Plant		200	100	300	150	160	80		
Reissue		300	150	500	250	600	300	<del></del>	
Provisional		200	100	0	0	0	0		
2. EXCESS CLA	IM FEES							Fee (\$)	Small Entity Fee (\$)
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3. APPLICATION		—							
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listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
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4. OTHER FEE(S		#12A *	(ma am11 **		4			Fees	Paid (\$)
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SUBMITTED BY	illa .				Registration No.		T	(0.15) 5 =	
Signature	THU	M	7		Attorney/Agent)	47,580	Telephone	(617) 95	1-7000
Name (Print/Type)	Gloria Fuente	es					Date	March 8	, 2006

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2 Sheet 1

Complete if Known				
Application Number	09/376,604			
Filing Date	August 18, 1999			
First Named Inventor	Ragupathy Madiyalakan			
Art Unit	1642			
Examiner Name	G. B. Nickol			
Attorney Docket Number	AREX-P03-004			

	U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	AA	US-5,240,833	08-31-93	Nudelman		
	AC	US-5,807,978	09-15-98	Kokolus		
	AD	US-6,088,613	07-11-00	Unger		

	FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	BA	EP 0 153 871 A2	09-04-1985	Chang			
	BB	EP 0 315 456 B1	05-10-1987	Fagnani			

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	ALGARRA et al., 1997, Altered MHC class I antigens in tumors, Int. J. of Clin & Lab. Res. 27:95-102 (Abstract only)	
	СВ	ANTONIA et al., 1995, Mechanisms of immune tolerance induction through the thymic expression of a peripheral tissue-specific protein, Int. Immunol. 7(5):715-725	
	CC	BAUM, 1994, Activating Anti-Idiotypic Human Anti-Mouse Antibodies for Immunotherapy of Ovarian Carcinoma, Cancer 73:1121-1125	
	CD	BENICHOU et al., 1994, Disruption of the determinant hierarchy on a self-MHC peptide: concomitant tolerance induction to the dominant determinant and priming to the cryptic self-determinant, Int. Immunol. 6(1):131-138	
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	СН	JACOBS and HASKELL, 1991, Clinical Use of Tumor Markers in Oncology, Curr. Probl Cancer 15(6):299-360	
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	CJ	LEE et al., 1999, Increased Vaccine-Specific T Cell Frequency After Peptide-Based Vaccination Correlates with Increased Susceptibility to In Vitro Stimulation But Does Not Lead to Tumor Regression, J. Immunol. 163:6292-6300	

Examiner	Date
Signature	Considered

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Sut	ostitute for form 1449A/B/PT	0		Complete If Known		
				Application Number	09/376,604	
l IN	NFORMATION	I DI	SCLOSURE	Filing Date	August 18, 1999	
l s	TATEMENT E	3Y /	APPLICANT	First Named Inventor	Ragupathy Madiyalakan	
				Art Unit	1642	
	(Use as many sh	eets as	s necessary)	Examiner Name	G. B. Nickol	
Sheet	2	of	2	Attorney Docket Number	AREX-P03-004	

СК	NISHIMURA et al., 2000, The critical role of TH1-dominant immunity in tumor immunology, Cancer Chemother. Pharmacol. 46(Suppl):S52-S61
CL	ÖHLÉN et al., 2001, Expression of a Tolerizing Tumor Antigen in Peripheral Tissue Does Not Preclude Recovery of High-Affinity CB <sup>+T</sup> Cells of CTL Immunotherapy of Tumors Expressing the Antigen, J. Immunol. 166:2863-2870
CM	PANI, 1994, Failure of presented, nondominant self epitope to induce tolerance – implications for autoimmune-diseases, Immunological Investigations 23:337-346 (Abstract only)
	SEMINO et al., 1993, Heterogeneity of the alpha-interferon-mediated overexpression of class-I and class-II major histocompatibility complex molecules in primary cultured cancer cells, J. Biol. Reg. & Homeo. Agents 7:99-105
СО	WATTS and LANZAVECCHIA, 1993, Suppressive Effect of Antibody on Processing of T Cell Epitopes, J. Exp. Med. 178:1459-1463

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.